Update on Quantitative Test Kits for the Detection of Genetically Engineered Events

GRAIN INSPECTION ADVISORY COMMITTEE MEETING

OCTOBER 27, 2015

Dr. Tandace Bell, Chief
Biotechnology and Analytical Services Branch

Importance of Detection Techniques for Genetically Engineered (GE) Grain

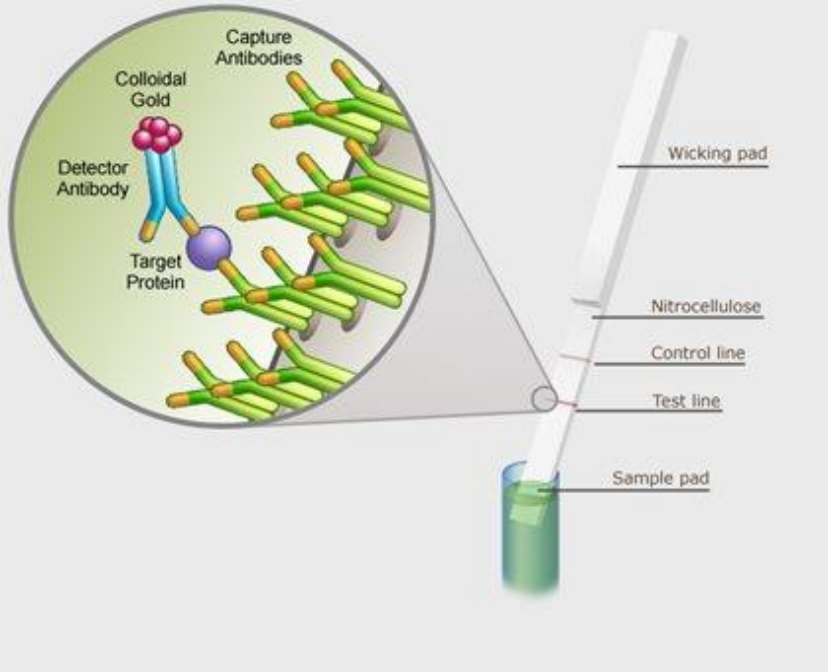
To distinguish biotech from conventional crops, we need tests that are:

- Accurate
- Reliable
- Cost-effective
- Market compatible

Protein-based Detection Facilitates Rapid, Onsite Measurements

Function and utility of lateral flow strips (LFS):

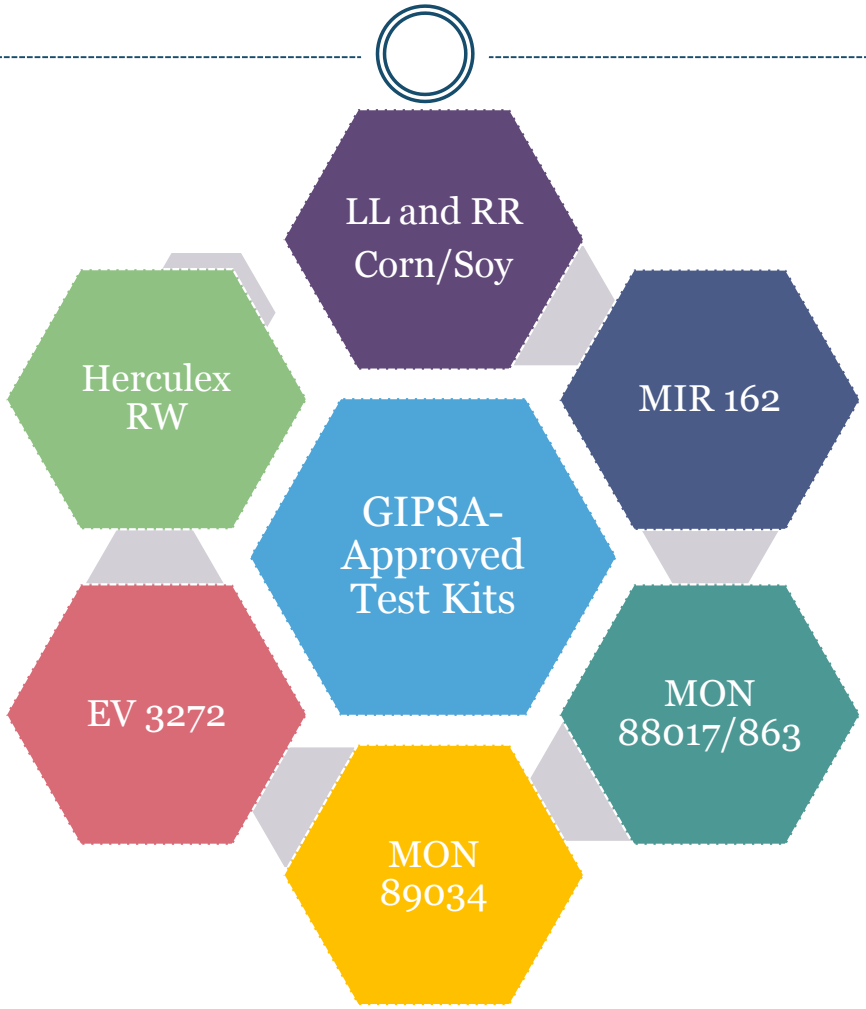
- Specificity (limited)
- Sensitivity (limited)
- Cost-effective
- Suitable for field testing



GIPSA's Biotechnology Qualitative Rapid Test Kit Evaluation Process

- Manufacturer submits data package supporting their claims for GIPSA review
- GIPSA verifies performance:
  - 120 independent analyses, using three different test lots, 40 samples for each lot. All results must be negative
  - 120 independent analyses, using three different test lots, 40 samples for each lot, at the claimed detection threshold. All results must be positive
- If claims verified by GIPSA, a certificate of performance (COP) is issued

Current GIPSA-Approved Qualitative Rapid Test Kits



Update on Comparison Between Protein-based and DNA-based Methods

- Analysis of quantitative LFS to compare manufacturer's samples and GIPSA-generated samples
- Compare protein-based method (LFS) to DNA-based method (PCR)
- Determine optimal particle size for most accurate results using LFS
- Perform statistical analysis on data to determine concordance between DNA-based method and LFS
- Initiate survey study using "real-world" grain samples

Technical Challenges Related to Quantitative Rapid Test Kits

- Specificity
  - Multiple traits can express the same protein
  - Stacked events-how to quantify?
- Sensitivity
  - LFS less sensitive than DNA-based methods
  - Different and/or low protein expression rates
- Calibration
  - No protein-based certified reference material available
  - Calibrants used must be DNA-based

Questions?